REMARKS

In summary, the final Office Action rejected all pending claims 35-80 except five (claims 36, 48, 52, 64 and 68 – which were merely objected to).

Applicants respectfully request entry and favorable consideration of the present Amendment After Final which is presented in a form that is intended not to raise additional issues requiring search and which was not earlier presented due to the prior procedural posture of the application.

The amendments presented herewith essentially cancels all prior independent claims and incorporates the limitations thereof into the claims depending directly and indirectly therefrom and thus all such claims are allowable as well.

With respect to the remaining claims they have been amended to depend directly or indirectly from one of the allowable claims thus rendering each such claim allowable too.

In addition, Applicants hereinbelow recite portions of the Summary of the Invention to provide some measure of context for certain of the allowable claims. At one level, the Summary reinforces the notion that capture of "noise" (as very broadly defined in the application as filed) helps provide an accurate interpretation and reconstruction of sensor-derived physiologic data. Thus, the invention is not limited merely to subcutaneous electrodes capturing cardiac ECG data, but electrodes in addition to many other types of sensors too.

The excerpt of the Summary of the Invention (with *emphasis added*) follows.

Summary of the Invention

A system and method for storing and communicating information regarding the type of conditions that existed contemporaneously with the recording of an ECG signal is described. As discussed above, during the recording of ECG segments, a variety of information is lost in the normal use of [sic] subcutaneous and other ECG monitors. This information includes both trigger events, *and/or non-physiologic noise* conditions present when the ECG signal is being recorded. According to one aspect of the invention, this information may be captured with the ECG signal and made available to the clinician as screen data or on an electrocardiogram tape recording, for example. This information

is stored in a manner that accommodates the nature of the data compression and data communication requirements of the medical device.

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According to another aspect of the system, *noise is recorded with the physiological signal, including noise caused by Electronic Article Surveillance (EAS), ElectroMagnetic Interference (EMI) noise, ElectroMyographic (EMG) noise, spurious electrode/tissue movement, pacing spikes, defibrillator spikes, and so forth*. A series of filters or [sic] filter taps can be used, together with digital signal processing if desired, to determine the nature of these noise signals as they are occurring.

The noise may be categorized in preferred embodiments by using knowledge about the temporal frequency characteristics of the noise. For example, EMG noise [sic] is broad band and can be characterized by broadband filters. As another example, pacing and defibrillator spikes are generally high voltage and current and of regularized or expected duration. EMI is generally high frequency and appears in bursts.

According to another aspect of the invention, recorded noise pulses may be used to logically reject future noise present in the high-level arrhythmia detection logic that may be used to automatically trigger an electrogram storage period.

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A wide variety of useful adjunct sensors including sensors for edema, pressure, temperature, cardiac output, blood flow, oxygen saturation of the blood, pH, ischemia in the heart, motion or activity, and other sensors may be used with the inventive system. The combining of contemporaneous information from such sensors with triggered electrograms enhances the ability to diagnose the electrogram. It should also be noted that the data can be stored in parallel, if desired, such that two memory buffers can be filled, one with the ECG data and one with the sensor data. This could be particularly advantageous for a pressure wave signal, for instance.

In one embodiment, the information that is recorded in real-time while the ECG signal is being monitored is stored in the ECG memory area as a set of coded markers within the data itself. These markers, which are set to predetermined, off-limit values, replace data points in the compressed and sampled signal.

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If noise is present in the input signal, the device can respond by eliminating R-wave detection signals or by modifying the patterns of acceptable auto trigger responses to apparent R-waves in the presence of noise, which may affect which segments of the ECG will be recorded. In such cases, no data may be stored if the trigger event does not occur.

According to yet another aspect of the invention, other data may be captured along with noise, including additional physiologic condition sensor data, apparent R-waves which may be used for the arrhythmia triggers, indications of losing contact with the body by the electrodes, detecting pacing pulses, defibrillation pulses, low battery and other internal to the device conditions and so on. Other types of signals that may be recorded include ElectroMyoGraphic (EMG) noise from muscle activity, artifact noise from electrode motion within the body, loss or change in the electrode/body contact,

pacemaker pulses, defibrillator pulses, and Electro-Magnetic Interference (EMI), which can be of a wide variety of types from different sources. Any combination of such data may be stored in various preferred embodiments of the present invention.

CONCLUSION

Applicants respectfully assert that all presenting pending claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims so they may proceed to timely issuance as U.S. Letters Patent. Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

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